K050056

JUN 2 1 2005

Attachment 6

510(k) Summary

Submitter: Nonin Medical, Inc.

Contact Person:
Lori Roth
Clinical/Regulatory Specialist
Nonin Medical, Inc.
13700 1st Ave North
Plymouth, MN 55441-5443

Date Prepared: January 7, 2005

Trade Name: Model 2500A PalmSAT® Pulse Oximeter

Classification Name: and Number: Class II, 21 CFR 870.2700

Product Code: 74 DQA

Predicate Device(s): The predicate devices are the Model 2500 PalmSAT® Pulse Oximeter, K001930, cleared on July 22, 2000 and the Model 2500 PlamSAT® Pulse Oximeter with 2500C and 2500B, K002690, cleared on October 11, 2000.

Device Description: The Model 2500A PalmSAT® with Alarms is a digital handheld pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate using one of a range of Nonin compatible oxygen sensors. It features an easy-to-read display that presents patient data and status information. The display features light-emitting diodes (LED) that show the SpO_2, pulse rate values, tricolor pulse quality indicator, alarm bar, alarm silence indicator, and low battery indicator.

New Features

- Patient-specific audible and visual high priority alarms.
- Equipment-specific audible and visual medium priority alarms.

- User selectable high and low alarm limits for SpO_2 and pulse rate.
- The ability to review and recall previous alarm limits and volumes.
- Variable pitch audible pulse beep indicator with an adjustable volume
- Visual and audible (adjustable volume) alarms.
- An alarm silence feature: silences audible alarms for the first 2 minutes of normal operation and on-demand.
- Enhanced signal processing

The Model 2500A will typically operate for 60 hours continuously between alkaline battery replacements, or for 40 hours with the Model 2500B Rechargeable NiMH (Nickel Metal Hydride) Battery Pack (optional). The 2500A requires no routine calibration or maintenance other than replacement of the alkaline batteries or recharging the optional battery pack.

The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.

Indications for Use:

The Nonin® Model 2500A Pulse Oximeter with Alarms is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, and neonatal patients. It is intended for spot-checking and / or continuous monitoring of patients during motion and no motion conditions, and for patients who are well or poorly perfused.

Functional and Safety Testing:

Nonin's 2500A Pulse Oximeter has successfully undergone both bench and human testing to support the determination of substantial equivalence. Human oxygenation evaluations were conducted to confirm conformance to accuracy and precision specifications.

Conclusion:

Nonin's Model 2500A Pulse Oximeter is substantially equivalent to the predicate devices in terms of accuracy, functional design and principles of operation. Performance test results do not raise new questions of safety and effectiveness when compare to the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2005

Ms. Lori Roth
Clinical/Regulatory Specialist
Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minnesota 55441-5443

Re: K050056
Trade/Device Name: Model 2500A Palmsat Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 27, 2005
Received: May 31, 2005

Dear Ms. Roth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

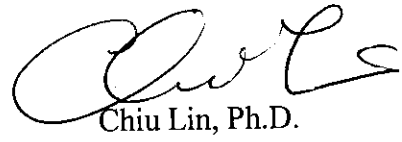
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)	K050056
Device Name	Nonin Medical, Inc. Model 2500A
Indications for Use	The Nonin® Model 2500A Pulse Oximeter with Alarms is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, and neonatal patients. It is intended for spot-checking and / or continuous monitoring of patients during motion and no motion conditions, and for patients who are well or poorly perfused.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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